UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *"Track One Cases"*	MDL No. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

MALLINCKRODT'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT

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Mallinckrodt LLC, SpecGX LLC, and Mallinckrodt plc[1] ("Mallinckrodt") fully join the joint briefs on behalf of Manufacturer Defendants and all Defendants. Mallinckrodt writes separately to identify additional, unique bases for the dismissal of the claims against it.

INTRODUCTION

Plaintiffs have done their best to paint "the industry" with a broad brush, obscuring the meaningful differences between the dozens of disparate defendants. But by this stage of the litigation, Plaintiffs are required to adduce evidence in support of their claims *against each individual defendant*. This case is premised on alleged wrongful *conduct*—not a theory of strict liability for manufacturing legal products. To survive summary judgment, Plaintiffs must have assembled facts sufficient to support allegations of actionable, wrongful conduct as to Mallinckrodt specifically. They have not done so in several important respects.

As to Plaintiffs' marketing claims, the record offers no evidence that Mallinckrodt promoted its generic products to physicians at all, much less that it did so in a manner that was false or misleading. Accordingly, summary judgment should enter on that aspect of Plaintiffs' claims.

As to Plaintiffs' diversion theory, Plaintiffs have not identified a single suspicious order that Mallinckrodt allegedly shipped to any customer—nor a single shipment that Mallinckrodt made into Cuyahoga or Summit County in the last 20 years.[2] Moreover, Plaintiffs have developed no evidence that Mallinckrodt's anti-diversion program was deficient after 2012. Indeed,

[1] Mallinckrodt plc is an Irish company that is not subject to and contests personal jurisdiction for the reasons explained in its pending motion to dismiss for lack of personal jurisdiction; it is specially appearing to join this motion as a result of the Court's deadline to file dispositive and *Daubert* motions, and, thus, it does not waive and expressly preserves its pending personal jurisdiction challenge.

[2] Mallinckrodt shipped only one order into Cuyahoga county—a single shipment to the Cleveland Clinic in 1998 that Plaintiffs do not claim was suspicious. Pantina Decl. Ex. 1 (Cuyahoga sales data).

Plaintiffs' experts have *explicitly denied* holding the opinion that Mallinckrodt's anti-diversion program was in any way inadequate after 2012.

Summary judgment "is a tool to narrow the factual and legal issues to be brought to trial." *Riddle v. Egensperger*, 266 F.3d 542, 551 (6th Cir. 2001); *see also Wuliger v. Christie*, 310 F. Supp. 2d 897, 901 (N.D. Ohio 2004). This case desperately needs narrowing. After more than 13 months of discovery, it is clear that Plaintiffs lack the factual evidence necessary to prove that Mallinckrodt: (i) falsely marketed its generic products (it did not promote them at all), (ii) shipped any suspicious order to any customer, let alone a customer in Cuyahoga or Summit County, or (iii) had an inadequate anti-diversion program at any point after 2012. Judgment should enter for Mallinckrodt on at least those aspects of Plaintiffs' claims to narrow the focus of any trial.

LEGAL STANDARD

A Court must grant summary judgment where the "depositions, documents, electronically stored information, affidavits or declarations, stipulations [], admissions, interrogatory answers, or other materials" "show[] that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a), (c); *see also Scola v. Publix Supermarkets, Inc.*, 557 F. App'x 458, 462 (6th Cir. 2014). "[T]he mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff." *Univ. Hosp. Health Sys., Inc. v. Pohl Inc. of Am.*, 358 F. Supp. 3d 658, 662 (N.D. Ohio 2019) (quoting *Copeland v. Machulis*, 57 F.3d 476, 479 (6th Cir. 1995)).

ARGUMENT

I. Mallinckrodt is Entitled to Partial Summary Judgment on Plaintiffs' Marketing Claims Because Plaintiffs Have Failed to Adduce Evidence that Mallinckrodt Promoted its Generic Products.

Nearly all of Mallinckrodt's opioid sales were of *generic* opioids, which were *never promoted* to physicians. Indeed, the undisputed evidence shows that Mallinckrodt's only opioid promotion was limited to its very few branded opioid products.[3] Accordingly, the Court should enter partial summary judgment in Mallinckrodt's favor on Plaintiffs' marketing-based claims as to its generic drugs.

Simply put, Plaintiffs' allegations of false or misleading marketing have no applicability to the vast majority of Mallinckrodt's sales. ***More than 99.7%*** of the opioids Mallinckrodt sold were generic medications,[4] which Mallinckrodt did not promote to physicians. Pantina Decl. Ex. 4 (Collier Dep. Tr.) at 253:13-19. As Plaintiffs own experts concede, generic manufacturers like Mallinckrodt do *not* try to grow the market for generic opioids by educating doctors on the risks and benefits of its generic products. Pantina Decl. Ex 5 (Perri Dep. Tr. Vol. 2) at 547:15–548:8. Rather, Mallinckrodt sells its generic opioid medications to DEA-registered wholesalers,

[3] The Complaint alleges that, in addition to generic opioids, Mallinckrodt manufactured and sold two branded opioids: Exalgo and Xartemis. Summit Compl. ¶ 101. Although Mallinckrodt's promotion of Exalgo and Xartemis was completely consistent with their FDA-approved labels and included appropriate warnings, Mallinckrodt recognizes that Plaintiffs would likely dispute that contention and respects the Court's instruction to be selective in identifying bases for summary judgment. Accordingly, this individual motion focuses on marketing with respect to generic products only. However, Mallinckrodt joins other joint briefs that move for summary judgment on separate grounds applicable to the branded marketing claims. *See* Manufacturer Defendants' Brief in Support of Mot. for Summ. J. for Plaintiffs' Failure to Offer Proof of Causation; Combined Brief of Distributors and Manufacturers in Support of Partial Summ. J. on Statute of Limitations Grounds; Brief in Support of Manufacturers' Joint Mot. for Summ. J. on Plaintiffs' RICO, OCPA, and Conspiracy Claims; Manufacturer Defendants' Brief in Support of Mot. for Summ. J. that Plaintiffs' State-Law Claims are Preempted and Their Federal Claims Are Precluded; Manufacturer Defendants' Memo. in Support of Mot. for Summ. J. on Plaintiffs' Public Nuisance Claims.

[4] *See* Pantina Decl. Ex. 2 (slipsheet referencing MNK-T1_0007897646, which Mallinckrodt will submit in native format). This statistic is based on sales data for direct sales between 2006 and 2017, calculated as a share of dosage units, excluding generic methadone and its branded form, Methadose, which is an addiction *treatment* medication that Plaintiffs also exclude from their analysis. *See* Pantina Decl. Ex. 3 (Expert Report of Meredith Rosenthal, p. 37 and Attachment C).

distributors, and retail pharmacies, and—as with all generic products—it competes with other generic manufacturers based primarily on price, as well as on quality and service. Pantina Decl. Ex. 6 (Vorderstrasse Dep. Tr.) at 139:10-23. It is thus unsurprising that there is no evidence that Mallinckrodt promoted its generic opioids to prescribers—without whom there can be no prescription to fill—much less that it did so in a false or misleading fashion.

In addition, all labeling for generic prescription medications, including opioids, must be approved by the FDA as part of the drug approval process, 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 314.94, and generic manufacturers must abide by the "duty of sameness" in keeping generic medications identical to their branded counterparts, 21 U.S.C. § 355(j)(2)(A)(i)-(iv); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613, 616 (2011). To the extent Plaintiffs allege that Mallinckrodt's labeling was misleading, those claims are preempted for all the reasons discussed in the Generic Manufacturers' Motion for Partial Summary Judgment. This Court should accordingly grant summary judgment for Mallinckrodt on Plaintiffs' marketing claims to the extent they are based on Mallinckrodt's generic opioid products.

II. Mallinckrodt is Entitled to Summary Judgment on Plaintiffs' Claims Premised on a Diversion Theory Because Plaintiffs Have Failed to Adduce Evidence that Mallinckrodt Shipped Any Suspicious Orders or that Its Anti-Diversion Program was Deficient after 2012.

After months of extensive discovery, Plaintiffs have failed to identify ***a single suspicious order*** that Mallinckrodt shipped to any customer, much less a customer in Cuyahoga or Summit County. Perhaps most tellingly, Plaintiffs' own experts have expressly declined to conclude that Mallinckrodt's anti-diversion program was in any way deficient since 2012. Indeed, the record is completely devoid of any evidence suggesting any deficiency in Mallinckrodt's anti-diversion program in the last seven years. The Court should accordingly grant summary judgment for Mallinckrodt on Plaintiffs' diversion-based claims related to orders placed after 2012.

A. Plaintiffs Have Failed to Identify a Single Suspicious Order that Mallinckrodt Shipped, Much Less One After 2012.

Plaintiffs' diversion claims are purportedly grounded in Mallinckrodt's supposed failure to halt and report shipments of suspicious orders, allegedly in violation of the Controlled Substances Act and its implementing regulations. *See* Summit Compl. ¶ 504. But Plaintiffs are missing the most basic element of their claim: a suspicious order. After months and months of discovery, and more than 30 depositions of Mallinckrodt witnesses, Plaintiffs have failed to identify a single suspicious order that Mallinckrodt purportedly shipped to any of its customers.

Although Plaintiffs' written discovery responses promised that their experts would identify suspicious orders that Mallinckrodt shipped,[5] Plaintiffs' expert reports are deafeningly silent. In fact, none of Plaintiffs' four experts opining on diversion issues identify in his or her expert report a single suspicious order that Mallinckrodt supposedly shipped. Indeed, Plaintiffs' primary expert on suspicious order monitoring, Mr. Rafalski, admitted in his deposition that he is not able to identify any suspicious orders at all shipped by Mallinckrodt (or any other Manufacturer Defendant for that matter). Pantina Decl. Ex. 9 (Rafalski Dep. Tr. Vol. 2) at 635:2-13 ("Q. Okay. And are you offering any opinion in this litigation that any particular order shipped by a manufacturer into Summit or Cuyahoga County was suspicious? A. I'm sorry, shipped by a manufacturer -- Q. Correct. A. -- to a distributor? Q. That's right. To -- to someone in Cuyahoga or Summit County. A. No, sir.").

Similarly, Plaintiffs' experts do not identify a single suspicious order placed to Mallinckrodt that the company failed to report to DEA. To the contrary, the uncontested record evidence demonstrates that Mallinckrodt never shipped any suspicious order. Pantina Decl. Ex.

[5] *See* Pantina Decl. Ex. 7 (Summit County's Suppl. Resp. to Manufacturer Defendants' Interrog. No. 27); Pantina Decl. Ex. 8 (Cuyahoga County's Suppl. Resp. to Manufacturer Defendants' Interrog. No. 28).

10 (Harper Dep. Tr.) at 442:6-9. Without record evidence that Mallinckrodt ever shipped a suspicious order, a jury cannot find the facts sufficient to sustain Plaintiffs' diversion claims against Mallinckrodt.

What's more, except for a single (totally innocuous) order shipped to the Cleveland Clinic in 1998, Mallinckrodt never shipped any opioid products into Summit or Cuyahoga counties, at any time. Pantina Decl. Ex. 1 (Cuyahoga direct sales data). Instead, Mallinckrodt sold its opioid products to DEA-registered distributors, wholesalers, and the distribution centers of retail pharmacy chains—and not to independent pharmacies that dispense products to patients. Pantina Decl. Ex. 6 (Vorderstrasse Dep. Tr.) at 139:10-23. Orders that Mallinckrodt received were shipped to the locked vaults at Mallinckrodt's customers' warehouses and no farther. Only after Mallinckrodt's *customers* received orders for that product—orders that Mallinckrodt *did not* see and that first passed through the DEA-registered customers' suspicious order monitoring system—would Mallinckrodt's product leave that customer's warehouse and travel to a pharmacy where it could be dispensed to a patient who presents a valid prescription. The Manufacturer Defendants have filed a separate brief addressing Plaintiffs' failure to show causation—including the failure to connect any shipment by a manufacturer to any harm in Cuyahoga and Summit Counties—and Mallinckrodt refers to and incorporates that brief by reference. *See* Manufacturer Defendants' Brief in Support of Mot. for Summ. J. for Plaintiffs' Failure to Offer Proof of Causation. In short, Plaintiffs have failed to connect any shipment by *Mallinckrodt*, much less a suspicious one, to diversion in the relevant geography, providing yet another basis for summary judgment.

B. As Plaintiffs' Experts Agree, the Record Provides No Basis to Find that Mallinckrodt's Anti-Diversion Efforts after 2012 Were Inadequate.

Unable to identify a single instance in which Mallinckrodt failed to halt or report a suspicious order, Plaintiffs resort to the vague, hail-Mary assertion that Mallinckrodt allegedly

failed to "maintain controls against diversion." *See* Summit Compl. ¶¶ 512, 516. However, even *Plaintiffs' own experts* declined to conclude that Mallinckrodt's anti-diversion program was in any way deficient after 2012.

After months of sweeping discovery and depositions of more than 30 company witnesses, Plaintiffs cannot substantiate their allegation that Mallinckrodt's anti-diversion program was deficient at any time since 2012. Tellingly, both experts retained by Plaintiffs to opine on the alleged insufficiency of Defendants' controlled substances compliance programs conceded that they are *not* offering any opinion that Mallinckrodt's anti-diversion program was insufficient or ineffective after 2012. Pantina Decl. Ex. 9 (Rafalski Dep. Tr. Vol. 2) at 665:19-666:8 ("Q. Okay. So fair to say in this litigation, you're not providing any opinion with respect to Mallinckrodt's suspicious order monitoring program after 2011? . . . A . . . so that would be an accurate statement as of today."); Pantina Decl. Ex. 11 (Whitelaw Dep. Tr. Vol. 2) at 938:9-13 ("Q. Are you stating today that you cannot offer an opinion as to the adequacy of Mallinckrodt's anti-diversion program post 2012? A. That is what I'm saying. . . ."). Neither Mr. Rafalski nor Mr. Whitelaw testified to *any* deficiencies in Mallinckrodt's anti-diversion program after 2012.

Plaintiffs likewise have failed to adduce factual support for any alleged deficiency. The uncontested record evidence shows that Mallinckrodt had a robust anti-diversion program that—as early as 2010—included voluntary chargeback review and reporting of downstream registrants. Pantina Decl. Ex. 12 (Gillies Dep. Tr. Vol. 1) at 221:7-18. Mallinckrodt reported to DEA the results of its monitoring, Pantina Decl. Ex. 10 (Harper Dep. Tr.) at 374:10-17,[6] and DEA was appreciative. Indeed, in response to learning about Mallinckrodt's chargeback review initiative in

[6] *See also* Pantina Decl. Ex. 13 (November 1, 2010 letter from Mallinckrodt to DEA St. Louis Division Office, at Bates begin MNK-T1_0000373856); Pantina Decl. Ex. 14 (November 1, 2010 letter from Mallinckrodt to DEA Albany Division Office, at Bates begin MNK-T1_0000288483).

2010, the St. Louis DEA Diversion Program Manager told Mallinckrodt that it had "the best" process that he had seen to date and "what he expected from Mallinckrodt as an industry leader." Pantina Decl. Ex. 15 (Harper notes from November 1, 2010 meeting at DEA St. Louis Office, Bates begin MNK-T1_0000421974). Even Plaintiffs' expert Mr. Whitelaw admitted that he "did not find flaws" with respect to Mallinckrodt's chargeback restriction program; the only "flaw" in the program, according to Mr. Whitelaw, was that Mallinckrodt did not implement chargeback review earlier. Pantina Decl. Ex. 11 (Whitelaw Dep. Tr.) at 944:22-945:23. With no expert opinion that the Company's anti-diversion program was deficient after 2012, and no factual evidence of any deficiencies in the record, Plaintiffs cannot substantiate the allegations in their Complaint. Accordingly, the Court should grant summary judgment in Mallinckrodt's favor on all diversion-based claims at the very least as to the time period after 2012.

CONCLUSION

Summary judgment should enter for Mallinckrodt on Plaintiffs' marketing claims to the extent they are based on Mallinckrodt's generic opioid products and on Plaintiffs' diversion claims at the very least as to the time period after 2012.

Dated: June 28, 2019

Respectfully submitted,

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LOCAL RULE 7.1(f) CERTIFICATE OF SERVICE

Pursuant to the Court's Order Regarding Pretrial Motions for "Track One" Trial, ECF # 1653, individual defendants have 18 pages for summary judgment motions. This brief adheres to the limits set forth in that order, as it totals 8 pages.

Dated: June 28, 2019

/s/ Brien T. O'Connor
Brien T. O'Connor

CERTIFICATE OF SERVICE

I, Brien T. O'Connor, hereby certify that the foregoing document was served via file transfer protocol and email to all counsel of record.

/s/ Brien T. O'Connor
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